

## **Remarks**

### **Status of the Claims**

Claims 1, 7, 13, 17, and 19 have been amended. Claims 2 and 3 have been canceled without prejudice or disclaimer of the subject matter contained therein. Representative support for the amendments to the claims can be found at page 8, lines 27-32, and claims 2 and 3 as originally filed. The amendments to the claims do not add new matter.

### **Rejection under 35 USC § 112, second paragraph**

Claims 7 and 13 are rejected for allegedly being indefinite by failing to particularly point out and distinctly claims the subject matter regarded as the invention.

Claim 7 has been rejected for reciting a monoclonal antibody without defining the monoclonal antibody. Without acquiescing to the merits of the rejection, claim 7 has been amended. It is respectfully submitted that the amendments to claim 7 have overcome the basis for this rejection.

Claim 13 has been rejected for referring to an element that lacks antecedent basis. Without acquiescing to the merits of the rejection, claim 13 has been amended. It is respectfully submitted that the amendments to claim 13 have overcome the basis for this rejection. Therefore, Applicants respectfully request that these rejections be withdrawn.

### **Rejection under 35 USC § 112, first paragraph**

A. Claims 1-4, 17, and 19 are rejected for allegedly failing to comply with the written description requirement.

The Office Action alleges that Applicant's are not within possession of the claimed invention due to one skilled in the art allegedly not being able to envision the the contemplated genuses of "Th1 and Th2 mediated diseases" and "antagonists."

The claims, as amended, do not recite "Th1 or Th2 mediated diseases, thereby obviating the basis for this rejection. With respect to the term "antagonist", it is respectfully submitted that this term is abundantly clear in the art. Simply, an antagonist is a molecule with binding affinity for a target molecule but with no efficacy on the target molecule. One skilled in the art can immediately determine what is envisioned by the term "antagonist", and would further recognize that it does not need to be of a particular class of compounds. Antagonists are identified by the ability to specifically bind with either no efficacy or with the opposite effect of the normal binding partner. The key feature of the claimed invention is that CCR5 is rendered inoperable by the antagonist, and one of skill in the art would

recognize that the actual means by which CCR5 is antagonized can be easily achieved through a number of different manners. Moreover, the specification clearly illustrates numerous examples of multiple classes of antagonist (*see*, page 17, lines 11-26). Such antagonists are already known and understood by one of skill in the art. As to the claims potentially encompassing future identified antagonists, it is respectfully submitted that such compounds would be immediately recognizable as relevant to the claimed method by virtue of the fact that they antagonize CCR5. The claimed invention is directed to a method, not to potential future compounds, and as such, one of skill in the art can readily apply all CCR5 antagonists. Accordingly, it is respectfully submitted that the claims satisfy the written description requirement and Applicants request that this rejection be withdrawn.

B. Claims 1-4, 17, and 19 are rejected for allegedly failing to comply with the enablement requirement.

The Office Action alleged that the claimed invention does not enable one of skill in the art to “prevent” diseases. Without acquiescing to the merits of this rejection, Applicants have amended the claims. Applicants believe that the amendments to the claims have addressed the basis for this rejection. It is therefore respectfully requested that this rejection be withdrawn.

#### Rejection under 35 USC § 102(e)

A. Claims 1-14, 17, and 19 are rejected as allegedly being anticipated by Teeling.

The claimed invention, as amended, recites detecting for elevated INF- $\gamma$  or IL-13 levels in a subject to determine if CCR5 antagonist therapy is appropriate. Teeling does not describe detecting elevated INF- $\gamma$  or IL-13 levels and administer to a subject with elevated IFN  $\gamma$  and/or IL-13 levels. Accordingly, Teeling cannot anticipate the claimed invention. It is therefore respectfully requested that this rejection be withdrawn.

B. Claims 1-4, 17, and 19 are rejected as allegedly being anticipated by Shiota.

The claimed invention, as amended, recites detecting for elevated INF- $\gamma$  or IL-13 levels in a subject to determine if CCR5 antagonist therapy is appropriate. Shiota does not describe detecting elevated INF- $\gamma$  or IL-13 levels and administer to a subject with elevated IFN  $\gamma$  and/or IL-13 levels. Accordingly, Shiota cannot anticipate the claimed invention. It is therefore respectfully requested that this rejection be withdrawn.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicant respectfully requests entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,  
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